

Application Number 10/731,868  
Response to Office Action mailed September 24, 2007

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**REMARKS**

This paper is responsive to the Office Action dated September 24, 2007. Applicant has added claim 31. Claims 1-17 and 24-31 are pending; of these, claims 13 and 14 are currently withdrawn.

**Objection to the Specification**

The Office Action objected to the amendment filed September 7, 2007 under 35 USC §132(a) as introducing new matter. Specifically, the Office Action objected to the introduction of the sentence, "As shown in FIG. 8, a majority of IMD 12A is located within a pocket behind the scalp flap created by incision 18" at the end of paragraph [0036] of Applicant's specification as filed.

Applicant respectfully traverses this objection. Information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter.<sup>1</sup>

In this instance, FIG. 8 is described as depicting an alternate implantation orientation of IMD 12A relative to IMD 12A as shown in FIG. 7.<sup>2</sup> The implantation procedure of IMD 12A is described as follows: "The procedure for implantation of IMD 12A is similar to the procedure for implantation of IMD 12. In particular, the surgeon makes an incision 18 in scalp 14, draws back scalp flap 20 and separates a part of scalp 14 from skull 22 to create a pocket. The surgeon inserts IMD 12A in the pocket."<sup>3</sup>

This description is equally applicable to FIG. 8 as it is to FIG. 7. FIG. 8 is described simply as illustrating a different implantation orientation of IMD 12A. The assertion that "the teaching of FIG. 7 method with the same device 12A does not necessarily translate to method described in connection with figure 8"<sup>4</sup> is incorrect. Contrary to this assertion, paragraph [0034] of Applicant's specification as filed clearly applies to IMD 12A in general, which is shown in both FIG. 7 and FIG. 8. Repeating the implantation procedure of IMD 12A as already described

<sup>1</sup> MPEP 2163.06.

<sup>2</sup> Applicant's specification as filed, paragraph [0036].

<sup>3</sup> Applicant's specification as filed, paragraph [0036].

<sup>4</sup> Office Action dated September 24, 2007, page 2.

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in paragraph [0034] would be redundant, particularly because the implantation procedure of IMD 12A described in paragraph [0034] is not explicitly limited to IMD 12A as shown in FIG. 7.

As described in paragraph [0034], an incision 18 is made and a part of scalp 14 is separated from the skull to form a pocket. As is clearly visible in FIG. 8, a majority of IMD 12A is located within such pocket behind the scalp flap created by incision 18. Thus, the addition of the sentence, "As shown in FIG. 8, a majority of IMD 12A is located within a pocket behind the scalp flap created by incision 18" at the end of paragraph [0036] of Applicant's specification as filed does not constitute new matter.

For at least these reasons, the amendment to the specification filed September 7, 2007 does not introduce new matter as required to support the objection under 35 USC §132(a). Applicant respectfully requests the Examiner withdraw this objection.

#### **Claim Rejection Under 35 U.S.C. § 112**

The Office Action rejected claims 1-12, 15-17, 24-27, 29 and 30 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses this rejection.

#### ***Placing a majority of the IMD in the pocket***

As discussed above with respect to the objection to the specification, the feature of placing a majority of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp is included in the application as originally filed and does not constitute new matter.

In the section titled, "Response to Arguments," beginning on page 2, the Office Action concluded that Applicant's argument regarding the term "majority" based on FIG. 8 is unpersuasive, and stated that only FIGS. 4-7 and 9 are described in conjunction with a pocket. The Office Action further stated that FIG. 8 is described as a different method of implanting, and concludes that, "the teaching of FIG. 7 method with the same device 12A does not necessarily translate to method described in connection with figure 8."

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Applicant respectfully traverses these conclusions. As discussed above with respect to the objection to the specification, the implantation procedure of IMD 12A described in paragraph [0034] is equally applicable to FIG. 8 as it is to FIG. 7.

As described in paragraph [0034], an incision 18 is made and a part of scalp 14 is separated from the skull to form a pocket. As is clearly visible in FIG. 8, a majority of IMD 12A is located within such pocket behind the scalp flap created by incision 18. Thus, the feature of placing a majority of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp is supported by the application as filed, e.g., by paragraph [0034] and FIG. 8.

#### ***Recess and pocket***

With respect to claims 12 and 27, written description of the feature of placing an IMD within a recess is provided by, e.g., paragraph [0051] of Applicant's specification as filed. The Office Action argues that this is an alternative method of implantation. However, the context of paragraph [0051] of Applicant's specification as filed provides support for the combination of placing an IMD within a pocket and a recess. As stated in paragraph [0046] of Applicant's specification as filed, "In some cases, implantation of an IMD may include an extra surgical stage." Following the discussion of the use of a dummy IMD in paragraphs [0046]-[0050], paragraph [0051] states in part, "In addition, the surgeon may in some cases determine that the skull of the patient may be prepared to receive the IMD. The surgeon may, for example, create one or more troughs or recesses in the skull of the patient to receive the IMD or one or more modules thereof." (Emphasis added.) Clearly, in this context, Applicant's specification discloses the combination of a recess and a pocket.

#### ***Placing all of the IMD in the pocket***

With respect to claims 25, 26 and 29, written description of the feature of "placing all of" is provided by, e.g., paragraph [0022] of Applicant's specification as filed, which states, in part, "[t]he pocket may be opened sufficiently to receive IMD 12 or a portion thereof" (emphasis

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added). This statement illustrates that all or a portion of IMD 12 may be placed in a pocket. Applicant notes that mere rephrasing of a passage does not constitute new matter.<sup>5</sup>

The Office Action argued that this passage did not clearly suggest all of the device is inserted into the pocket. However, the term "or" in the phrase "IMD 12 or a portion thereof" (emphasis added) indicates that "a portion thereof" must mean something different than "IMD 12". Logically, since the reference to IMD 12 can not mean only a portion of IMD 12, it must be a reference to all of IMD 12. Instead of commenting on this seemingly obvious interpretation of the Applicant's specification, the Office Action simply focused on the term "received." Importantly, Applicant does not assert that the term "received" in itself supports the contention that the specification discloses that all of IMD 12 may be placed in a pocket. In the event this rejection is not withdrawn, Applicant respectfully requests the Examiner provide an explanation in support of an alternative interpretation of the phrase "IMD 12 or a portion thereof."

### ***Conclusion***

Each of the claims recites subject matter included in the present application as originally filed. For this reason, Applicant requests immediate withdrawal of each of the rejections under 35 U.S.C. 112.

### **Claim Rejection Under 35 U.S.C. § 102**

The Office Action rejected claims 1-3, 5-10, 12, 15-17 and 25-27 under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,648,914 to Berrang et al. (hereinafter "Berrang"). The Office Action also rejected claims 1-4, 7, 15 and 25-27 under 35 U.S.C. 102(e) as being anticipated by U.S. Pub. No. 2003/0109903 Berrang et al. (hereinafter "Berrang Application"). Applicant respectfully traverses the rejection. The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provide no teaching that would have suggested the desirability of modification to include such features.

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<sup>5</sup> *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973) as cited in MPEP 2163.07.

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***Claims 1-3, 5-10, 12, 15-17, 24 and 25***

Claim 1 recites placing a majority of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp.

Berrang and Berrang Application fail to disclose a pocket adjacent to the fold and between the scalp and the skull, or placing a majority of a low-profile implantable medical device in the pocket as recited by claim 1. In fact, neither Berrang nor Berrang Application demonstrate that there is any separation whatsoever between a scalp and skull behind a fold as recited in claim 1. Applicant notes that neither Berrang nor Berrang Application discusses any such separation. For example, in contrast to claim 1, Berrang illustrates in FIG. 3 that at least a substantial majority of the implant is placed in front the fold. Further, Berrang teaches that line 34 (FIG. 3) illustrates an incision whereby a surgeon raises a postauricular flap to facilitate the implantation.<sup>6</sup> Berrang teaches raising the postauricular flap, and placing the device beneath the flap, on the "flap" side of the fold. Berrang in no way suggests the additional step, after raising the flap, of creating a pocket adjacent to the fold and between the scalp and the skull. Because Berrang does not disclose creating a pocket, Berrang also does not disclose placing a majority of the low-profile implantable medical device in the pocket.

Similarly, Berrang Application also fails to teach or suggest such a feature. For example, as shown in FIG. 3 of Berrang Application, at least a substantial majority of the implant is placed in front the fold. Further, Berrang Application teaches that skin flap 23 is pulled back to facilitate implantation.<sup>7</sup>

Because Berrang and Berrang Application fail to disclose a pocket, or placing a majority of a low-profile implantable medical device in the pocket as recited by claim 1, Berrang and Berrang Application each fail to anticipate the Applicant's invention as recited in claim 1. For at least these reasons, the cited references fail to anticipate Applicant's claims 1-3, 5-10, 12, 15-17, 24 and 25 as required to maintain the rejection under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

<sup>6</sup> Berrang, column 13, lines 40-53.

<sup>7</sup> Berrang Application, paragraph [0056].

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***Claims 25 and 27***

Independent claim 26 recites placing all of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp.

In the rejection of claim 26, the Office Action states with reference to both Berrang and Berrang Application that "Figure 3 show (sic) an S-shaped incision and a pocket created right of the S-shaped incision, and adjacent a fold, in which all of the implant (as best understood by Applicant's specification) is placed into."<sup>8</sup>

However, as discussed with respect to claim 1, Berrang and Berrang Application each fail disclose placing a majority of a low-profile implantable medical device in the pocket. Applicant's invention as recited by claim 26 further requires placing all of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp.

In contrast to Applicant's invention as recited in claim 26, Berrang illustrates in FIG. 3 that at least a substantial majority of the implant is placed in front the fold. Further, Berrang teaches that line 34 (FIG. 3) illustrates an incision whereby a surgeon raises a postauricular flap to facilitate the implantation.<sup>9</sup> Likewise, as shown in FIG. 3 of Berrang Application, at least a substantial majority of the implant is placed in front the fold. Further, Berrang Application teaches that skin flap 23 is pulled back to facilitate implantation.<sup>10</sup>

In this manner, both Berrang and Berrang Application fail to anticipate Applicant's invention as recited by claim 26. For at least these reasons, the cited references fail to anticipate Applicant's claims 26 and 27 as required to maintain the rejection under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

**Claim Rejection Under 35 U.S.C. § 103**

The Office Action rejected claims 11, 24 and 28-29 as being unpatentable over Berrang or Berrang Application. The Office Action also rejected claim 30 as being unpatentable over U.S. Pat. No. 6,648,914 to Fischell et al. (hereinafter "Fischell") in view of Berrang. Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the

<sup>8</sup> Office Action dated September 24, 2007, page 6.

<sup>9</sup> Berrang, column 13, lines 40-53.

<sup>10</sup> Berrang Application, paragraph [0056].

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inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

### ***Claim 11***

As discussed previously in this response, Berrang and Berrang Application individually and collectively fail to disclose or suggest every element of independent claim 1. The rejection of claim 11 fails to overcome the deficiencies of Berrang and Berrang Application with respect to the elements of claim 1. For example, it would not have been obvious to one of ordinary skill in the art from the disclosures of Berrang and Berrang Application to separate a portion of the remainder of the scalp adjacent to the fold from the skull after separating the scalp flap from the skull to create a pocket adjacent to the fold and between the scalp and skull, and place a majority of a low-profile implantable medical device in such a pocket, as recited by independent claim 1. Because claim 11 is dependent on claim 1, the subject matter of claim 11 would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention.

For at least these reasons, the Office Action fails to establish a prima facie case for non-patentability of Applicant's claim 11 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

### ***Claims 24 and 28-29***

Independent claim 28 recites making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient. A similar feature is recited by claim 24, which is dependent on claim 1.

The Office Action acknowledges that such a feature is not disclosed by either Berrang or Berrang Application.<sup>11</sup> The Office Action further states that even though Berrang and Berrang Application disclose that the preferably located behind the ear (as show in FIG. 3), that it would have been obvious to locate the device on top of the head to improve the aesthetics of the implanted device.<sup>12</sup>

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<sup>11</sup> Office Action dated September 24, 2007, page 8.

<sup>12</sup> Office Action dated September 24, 2007, page 8.

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Applicant respectfully disagrees with this reasoning. First, Berrang and Berrang Application disclose that the device is preferably located behind the ear. Additionally, Berrang and Berrang Application provide no suggestion that locating the device elsewhere may improve the aesthetics of the implanted device. Indeed, Applicant does not see how simply relocating the device on the skull of a patient would improve the aesthetics of the implanted device as the implanted device still result in a lump at the new location. Instead, Berrang discloses that in some embodiments, skull bone may be excavated.<sup>13</sup> For this reason, if one of skill in the art sought to improve the aesthetics of the implanted device as suggested in the Office Action, one of skill in the art would not deviate from the preferred embodiment by relocating the device, but might instead excavate skull bone.

Furthermore, even if Berrang and Berrang Application did suggest relocating the implanted device, the references provide absolutely no suggestion that the device be relocated to the top of a head of a patient. In this manner, the Office Action appears to rely on Applicant's own disclosure as providing the motivation to locate an implanted device on the top of the head of the patient. This constitutes impermissible hindsight.

In addition, Berrang or Berrang Application teach away from the feature of making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient as recited by claim 21. Relocating components of the implanted devices described by Berrang and Berrang to the top of the head of the patient is impractical. For example, the implanted device disclosed by Berrang includes a microphone positioned adjacent an exterior auditory canal. The location of the microphone is integral to the operation of the implanted device.<sup>14</sup> The implanted device disclosed by Berrang also includes an electrode array in one of the cochlea scala.<sup>15</sup> Relocating components of the device to the top of the head of a patient as suggested by the Office Action would increase the distance wires would need to be run to connect the components.

For at least these reasons, the Office Action fails to establish a prima facie case for non-patentability of Applicant's claims 24 and 28-29 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

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<sup>13</sup> Berrang, column 10, lines 13-18.

<sup>14</sup> See, e.g., Berrang, column 6, line 47 to column 7, line 10.

<sup>15</sup> See, e.g., Berrang, abstract.



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### ***Claim 30***

As discussed previously in this Response, Berrang fails to disclose or suggest every element of independent claim 1. The rejection of claim 30 fails to overcome the deficiencies of Berrang with respect to the elements of claim 1. For example, it would not have been obvious to one of ordinary skill in the art from the disclosures of Berrang to separate a portion of the remainder of the scalp adjacent to the fold from the skull after separating the scalp flap from the skull to create a pocket adjacent to the fold and between the scalp and skull, and place a majority of a low-profile implantable medical device in such a pocket, as recited by independent claim 1. Because claim 30 is dependent on claim 1, the subject matter of claim 30 would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention.

For at least these reasons, the Office Action fails to establish a prima facie case for non-patentability of Applicant's claim 30 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

### **New Claims**

Applicant has added claim 31 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the references fail to disclose or suggest wherein the incision is a C-flap incision, as recited by claim 31. No new matter has been added by the new claims.

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### CONCLUSION

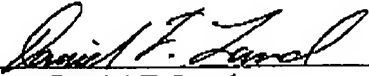
All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Applicant does not acquiesce with any of the Examiner's current rejections or characterizations of the prior art, and reserve the right to further address such rejections and/or characterizations.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: December 21, 2007

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